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10/087,049	03/02/2002	Chi Yung Fu		3263

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EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/087,049	Applicant(s) FU, CHI YUNG	
	Examiner Cheyne D. Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 10-12, 14, 16-24, 26-28, and 30 is/are rejected.
- 7) ☒ Claim(s) 5, 13, 15 and 25 is/are objected to.
- 8) ☒ Claim(s) 1-8, 10-28 and 30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments filed March 24, 2005 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. Newly submitted claim 29 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
3. Claim 29 is directed to "the artificial neural network...and at least two hidden layers between the input and output layers, while the elected invention is directed to an invention "with at least one of the input layer and a hidden layer." The distinct limitations support the undue search burden if they were examined together. This lack of overlapping searches documents the undue search burden if they were search together.
4. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 29 has been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
5. Claims 9 and 29 have been withdrawn.
6. Applicant's statement of claim 9 should be added back if its base claim is allowed has been acknowledged.
7. Claims 1-8, 10-28, and 30, living humans, staphylococcus aureus, diabetes, and acetone are examined on the merits.

8. FINAL OFFICE ACTION.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 1-4, 6-8, 10-12, 14, 23, 24, and 30 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Pavlou et al. (2000).

11. This rejection is maintained with respect to claims 1-4, 6-8, 10-12, 14, 23, 24, and 30, as recited in the previous office action mailed October 20, 2004.

RESPONSE TO ARGUMENTS

12. On page 7, Applicant argues that Pavlou et al. does not disclose the limitation of “an algorithm which intelligently adapts to an individual entity.” Applicant’s argument is not persuasive because the method and apparatus of Pavlou et al. comprise a 3-layer back propagation neural network (algorithm), a gas sensor array of high reproducibility, and a hybrid intelligent model, expert system (Abstract etc. and page 334). The intelligent system is applicable to determining a condition of a patient (individual entity or person) (page 341, column 1, lines 1-5) to address the need for “smart breath and clinical analysers” (page 340, column 2, last paragraph). The citation of a 3-layer back propagation neural network has been reasonably construed as an algorithm which intelligently adapts to an individual entity as described above.

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13. Further, Applicant argues that the claimed invention “is designed to deal with the problem of variation between individual.” It is noted that claims 1, 11, and 23 recite the limitation of “an algorithm which intelligently adapts to an individual entity.” However, said limitation is not limited to the argued limitation of “variation between individual” as argued by Applicant.

14. Applicant argues “Pavlou is trying to discriminate between six different bacteria based on odor detection.” Further, Applicant argues that the cited page 341, column 1, lines 1-5, and page 340, column 2, last paragraph, are “merely general statements about directions and goals of the industry. Pavlou does not actually show this.” Applicant’s arguments and pointed to disclosure in Pavlou et al. have been noted. However, Applicant’s argument is not persuasive because Pavlou et al. discloses further laboratory work and clinical tests are being undertaken to develop an expert system to govern the use of multiple parallel GA-NNs (algorithm) in each newly developed clinical test directed to a patient (page 340, column 2, lines 2-9).

15. Applicant argues “Pavlou describes a totally different type of algorithm, “a genetic algorithm. The adaptive learning of Pavlou et al. has nothing to do with adapting to the entity as done by Applicant.” Applicant’s argument is not persuasive because Pavlou et al. discloses further laboratory work and clinical tests are being undertaken to develop an expert system to govern the use of multiple parallel GA-NNs (algorithm) in each newly developed clinical test directed to a patient (page 340, column 2, lines 2-9).

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16. Therefore, the Office has established a prima facie case in regard to the instant prior art rejection.

17. Applicant's arguments directed to claims 5, 13, 15, and 25 have been found to be persuasive. Therefore, claims 5, 13, 15, and 25 have been withdrawn from the instant rejection.

BASIS FOR REJECTION

18. It is noted that the instant claims have been examined as directed to the elected species even though not all of the elected species have been specifically recited in said rejected claims. Further, the elected species of acetone has been reasonably construed as colorless, volatile, extremely flammable liquid ketone, CH_3COCH_3 , as defined by dictionary.com.

19. The method for Pavlou et al. is for determining a condition directed to *Staphylococcus aureus* as defined by the set of volatile markers such as ketones (acetone) described in Table 2, which represents the selection of a set of markers. The method of Pavlou et al. is directed to the non-invasive diagnosis of an infection (page 340, column 2, lines 5-7). The method and apparatus of Pavlou et al. comprise a 3-layer back propagation neural network (algorithm), a gas sensor array of high reproducibility, and a hybrid intelligent model, expert system (Abstract etc. and page 334). Pavlou et al. uses a specialized normalization algorithm (page 336, lines 1-3). The intelligent system is applicable to determining a condition of a patient (individual entity or person) (page 341, column 1, lines 1-5) to address the need for

“smart breath and clinical analysers” (page 340, column 2, last paragraph). Pavlou et al. discloses further laboratory work and clinical tests are being undertaken to develop an expert system to govern the use of multiple parallel GA-NNs (algorithm) in each newly developed clinical test directed to a patient (page 340, column 2, lines 2-9), as in claims 1, 4, 6, 7, 11, and 23.

20. Pavlou et al. discloses a 3-layer neural network is used to discriminate between pre-described classes and a correction algorithm for eliminating noise and errors (page 336, column 2, lines 1-21). The correction algorithm for eliminating noise and errors (page 336, column 2, lines 1-21) is directed to drift generated by a slow developing of the sensor material (environmental) (page 339, section 4.3), as in instant claims 2 and 14.

21. The intelligent system (artificial) is similar to the mammalian olfactory system (Abstract etc.), as in instant claims 3, 12, and 24.

22. The method of Pavlou et al. is an improvement the well known in the art “electronic noses” for determining diabetes (page 334, column 1, last paragraph, to column 2, line 2), as in instant claim 8.

23. Table 1 (page 334) discloses markers which correlate with a single condition (“supermarkers” as defined on page 6) and collective markers to indicate the condition of infectious disease (single condition), as in instant claim 10.

24. Pavlou et al. discloses a method for determining a condition directed to *Staphylococcus aureus* as defined by the set of volatile markers such as ketones (acetone) described in Table 2, as in instant claim 30.

CLAIM REJECTIONS - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

26. Claims 1-4, 6-8, 10-12, 14, 16, 17, 21, 22-24, 27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavlou et al. (2000) taken with Phillips (US 6,221,026 B1).

27. This rejection is maintained with respect to claims 1-4, 6-8, 10-12, 14, 16, 17, 21, 22-24, 27, and 30, as recited in the previous office action mailed October 20, 2004.

RESPONSE TO ARGUMENTS

28. Applicant argues that the “combination still does not contain the algorithm that adapts to the individual which is contained in all the claims.” Applicant’s argument has been considered and found to be unpersuasive because the argued limitation has been described by Pavlou et al. as discussed above.

29. Applicant argues “Phillips compares the data from patients with a disease to data from a set of 50 normal patients. Thus, there is no individualization by obtaining a baseline from a patient himself.” It is noted that the limitation of “obtaining a baseline from a patient himself” is not recited in the claims. Therefore, the recitation of the argued limitation from the prior art is required.
30. Specific to claim 27, Applicant’s argument of “in Phillips only the breath collector, not the detector as in claim 27, is heated” is not persuasive because claim 27 recites “a heater operatively connected to the volatile marker detector to refresh the detector” which is different from the argued limitation. Phillips describes an apparatus for the detection of volatile markers (artificial olfactory system) comprising a microprocessor-controlled device and a heated breath reservoir (column 10, lines 40-67 to column 11, lines 17), as in instant claim 27.
31. Applicant’s argument of the disclosure of Phillips “is not an artificial olfactory system but a standard chemical analysis tool.” It is noted that the claimed invention is directed to a method and apparatus for detecting the condition of an entity. Phillips describes a method directed to the diagnosis of disease by employing breath testing for the detection of particular diseases in humans. The method of Phillips provides an improvement for a simpler, safer, less painful and less expensive means screening for diseases (column 1, lines 4-43). An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement disclosed by Phillips for a simpler, safer,

less painful and less expensive means for screening diseases to improve the method of Pavlou et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a simpler, safer, less painful and less expensive means for screening diseases as taught by Phillips and Pavlou et al.

BASIS FOR REJECTION

32. Pavlou et al. describes the invention as recited in claims 1-4, 6-8, 10-12, 14, 23, 24, and 30.

33. Further, the method of Pavlou et al. is directed the ketone marker (acetone) (page 334, Table 2), as in instant claim 21.

34. However, Pavlou et al. does not describe the limitations recited in claims 16, 17, 22, and 27.

35. Phillips describes a method directed to the diagnosis of disease by employing breath testing for the detection of particular diseases in humans. The method of Phillips provides an improvement for a simpler, safer, less painful and less expensive means screening for diseases (column 1, lines 4-43).

36. Cell membrane fatty acids are degraded (destruction) to alkanes by lipid peroxidation (column 7, lines 31-39), as in instant claims 16 and 17.

37. Further, Phillips discloses oxygen free radical activity increases in ischemic heart disease (column 4, lines 37-39), as in instant claims 22.

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38. Phillips describes an apparatus for the detection of volatile markers (artificial olfactory system) comprising a microprocessor-controlled device and a heated breath reservoir (column 10, lines 40-67 to column 11, lines 17), as in instant claim 27.

39. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement disclosed by Phillips for a simpler, safer, less painful and less expensive means for screening diseases to improve the method of Pavlou et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a simpler, safer, less painful and less expensive means for screening diseases as taught by Phillips and Pavlou et al.

40. Claims 1-4, 6-8, 10-12, 14, 16-24, 27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavlou et al. (2000) taken with Phillips (US 6,221,026 B1) in view of Matteucci et al. (2000), and Kanety et al. (1994).

41. This rejection is maintained with respect to claims 1-4, 6-8, 10-12, 14, 16-24, 27, and 30, as recited in the previous office action mailed October 20, 2004.

RESPONSE TO ARGUMENTS

42. Applicant argues that Matteucci et al. “measures markers in the blood or urine...not the breath” and “Kanety detects insulin receptors from animal tissue; not breath”; therefore, there is no basis for combining the references with the others since they are directed to entirely different approaches.” Applicant’s argument is not persuasive. It is noted that Matteucci et al. and Kanety et al. describe approaches which requires an “invasive” type of diagnostic

tests. The method of Phillips is directed to the diagnosis of disease by employing breath testing for the detection of particular diseases in humans which is an improvement over the invasive tests of Matteucci et al. and Kanety et al. The method of Phillips “opens non-invasive window on normal metabolic pathways, and also illustrates how these pathways are altered in disease.” The non-invasive method of Phillips provides an improvement for a simpler, safer, less painful and less expensive means for screening for diseases. Further, said diagnoses have been confirmed in many different laboratories by employing progressively more sophisticated and sensitive assays (column 1, lines 4-43). Therefore, the cited description and motivation above would have motivated one of skill in the art at the time of the instant invention to improve on the clinical and diagnostic methods of Matteucci et al. (2000), Kanety et al. (1994), and Pavlou et al. for a simpler, safer, less painful and less expensive method.

BASIS FOR REJECTION

43. Pavlou et al. and Phillips describe the invention as recited by claims 1-4, 6-8, 10-12, 14, 16, 17, 21-24, 27, and 30.

44. However, Pavlou et al. and Phillips do not describe the invention as recited by claims 18-20.

45. Matteucci et al. discloses use of biological markers as major predictors of type 1 diabetes wherein blood glucose is measured and diabetic patients wherein diabetic patients had higher level of blood glucose than control subjects (Abstract etc.). Matteucci et al. hypothesized (predict) that oxidative stress even precedes diabetes (page 1182, column 2, lines 22-24) and enhanced levels of free radicals found in diabetes and impaired glucose tolerance have long

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been assumed to be related to chronically elevated glucose levels (page 1184, columns 2-3, Conclusions §), as in instant claims 18 and 19.

46. Kanety et al. discloses a method of using markers such as insulin receptors for diagnosing the effects of overeating as directed to diabetes mellitus, as in instant claim 20.

47. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement disclosed by Phillips for a simpler, safer, less painful and less expensive means for screening diseases (column 1, lines 4-43) to improve on the method of Pavlou et al., Matteucci et al., and Kanety et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a simpler, safer, less painful and less expensive means for screening diseases as taught by Phillips, Pavlou et al., Matteucci et al., and Kanety et al.

48. Claims 23, 24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavlou et al. (2000) taken with Phillips (US 6,221,026 B1) in view of Lewis (US006170318B1).

49. This rejection is maintained with respect to claims 23, 24, and 26-28, as recited in the previous office action mailed October 20, 2004.

RESPONSE TO ARGUMENT

50. Applicant argues that the “combination still does not contain the algorithm that adapts to the individual which is contained in all the claims.” Applicant’s argument has been

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considered and found to be unpersuasive because the argued limitation has been described by Pavlou et al. as discussed above.

BASIS FOR REJECTION

51. Pavlou et al. and Phillips describe the invention as recited by claims 23, 24 and 27.

52. However, Pavlou et al. and Phillips do not describe the invention as recited by claims 26 and 28.

53. Lewis describes a system for detecting analyte comprising an array of sensors (column 4, lines 19-31) wherein said system is used to monitor and detecting volatile markers from an individual patient (Figure 20) for disease monitoring as directed to said (column 20, lines 7-39). The detection device of Lewis which has a neural network is employed in a microwave oven (column 17, lines 59-66), as in instant claims 26 and 28.

54. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement disclosed by Phillips for a simpler, safer, less painful and less expensive means for screening diseases (column 1, lines 4-43) to improve on the method of Pavlou et al. and Lewis. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a simpler, safer, less painful and less expensive means for screening diseases as taught by Phillips, Pavlou et al., and Lewis.

CONCLUSION

55. Claims 5,13,15 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

56. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

57. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

58. This application contains claims 9 and 29 drawn to an invention nonelected, filed August 21, 2003. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

59. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO's official fax number is (571) 273-8300.

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60. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

61. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

62. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

63. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571)272-0718.

C. Dune Ly
6/9/05




ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER